

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 28 and 30 are currently amended. No new matter has been added. The specification supports the added limitation “fucose content of said antibodies is at least 20%” at page 2, paragraph [0023] (citing to published application US 2007-0015239).

A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Claims 1-57 are now pending in this application. Claims 1-27 and 33-57 are withdrawn as non-elected. Claims 28-32 are under examination.

I. STATEMENT REGARDING INTERVIEW UNDER 37 C.F.R. § 1.133(B)

Applicants’ Representative thanks Examiner Anne Gussow for the helpful and courteous interview of June 2, 2010. The substance of the interview is accurately stated in the Examiner Interview Summary dated March 23, 2010, and is set forth in more detail below.

II. CLAIMS 28-32 AS AMENDED ARE PATENTABLE

The present invention relates to Applicants’ discovery that higher fucose levels, i.e., 20% or more, can yield suitable effector activity provided that the fucose content/galactose content ratio is less than 0.6. See published application, page 1, paragraphs [0011] – [0012]. The prior art failed to disclose this phenomenon, and emphasized instead low fucose content. See published application, page 1, paragraphs [0008] – [0010].

In particular, the data in Table 1 of the present application (see published application, page 7) shows the unexpectedly high ADCC of antibodies with fucose content over 20% but with fucose/galactose ratio less than 0.6, as represented in FIG. 2.

In the final Office Action dated September 16, 2009, claim 28 stood rejected as anticipated by Shields et al., J. Biol. Chem., 2002, Vol. 277, pages 26733-26740 ("Shields").

Shields is irrelevant to the claims as amended, because Shields relates to improved ADCC of antibodies whose fucose level is low. Indeed, Shields in Table 1 discloses no more than 13% fucose when the fucose/galactose ratio is below 1.0. Therefore, Shields fails to satisfy the limitation "fucose content of said antibodies is at least 20%". Shields does not suggest this feature, and emphasizes low fucose levels. For example, Shields states that the Hu4D5 monoclonal antibodies expressed in Lec13 cells "consistently had about 10% fucosylated carbohydrate (Table I)". See page 26734, right column, lines 1-3 below "RESULTS".

In the final Office Action dated September 16, 2009, claims 28-32 stood rejected as anticipated by Shields in view of Shinkawa, et al., J. Biol. Chem., 2003, Vol. 278, pages 3466-3473 ("Shinkawa") and Cartron, et al., Blood, 2002, Vol. 99, pages 754-758 ("Cartron").

Here, absent Shields as basis for satisfying the limitation "fucose content of said antibodies is at least 20%", the Office could not account for this limitation in the other cited references.

Moreover, Shinkawa would have led a skilled artisan away from the present invention as claimed, because Shinkawa disclosed that galactose content has no relevance to ADCC. Shinkawa pointedly stated, "we could not find any correlation between the content of Gal and ADCC" (page 3471, right column, lines 10-11 from bottom).

Carton is completely silent regarding the glycosylation profile of monoclonal antibodies.

Taken together, Shields, Shinkawa, and Cartron do not establish a *prima facie* case of obviousness.

Accordingly, claims 28-32 are novel and non-obvious over Shields.

CONCLUSION

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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